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09/194,619	08/25/2003	Howard Kenneth Shapiro	P-1018	3413

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/194,619	SHAPIRO, HOWARD KENNETH	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/2/06, 10/17/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *9-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 17 October 2006 and 2 March 2006 have been entered. Claims 1 – 27 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450.

The examiner notes that because of applicant's lack of familiarity with the procedures of prosecution, multiple letters have been sent requesting further clarification of certain issues. While the case is now in condition for examination on the merits, substantial time has elapsed since the first office action on the merits. To expedite prosecution in the future, applicant should follow the rules set forth in 37 CFR, particularly rules 1.116 and 1.121, which relate to the manner of making amendments after final rejection and before final rejection respectively. To avoid making mistakes in the future, it is recommended that applicant submit a single set of claims with each amendment, rather than the multiple sets that have been submitted in the past.

Election/Restrictions

4. Claims 9 – 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 22 August 2005.

The restriction was made final in the Non-Final Office Action mailed 27 October 2005. Applicant is reminded that after a restriction is made final, the appropriate remedy is by petition rather than repeated complaints to the examiner. The restriction requirement was proper as the first claimed technical feature, a cell culture, is not a contribution over the prior art. Therefore the first claimed technical feature is not a special technical feature as defined by PCT Rule 13 and thus the invention lacks unity.

5. This application contains claims 9 – 27 drawn to an invention nonelected with traverse in the remarks filed 22 August 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Claims 1 – 8 are under examination.

Withdrawn Rejections and Objections

7. The objection to claim 1 is withdrawn as the spelling error has been corrected.

Maintained Rejections and Objections

Information Disclosure Statement

8. On pp. 36 – 37 of the remarks filed 2 March 2006, applicant questions "the Examiner's willingness to consider the disclosure on its merits" because the examiner pointed out that those references listed in the specification do not constitute a proper information disclosure statement (IDS). Applicant is directed to MPEP § 609, particularly subsection § 609.05(a) on non-complying IDSs. This section concludes with the statement:

> If information listed in the specification rather than in a separate paper, or if the other content requirements as discussed in MPEP § 609.04(a) are not complied with, the information need not be considered by the examiner, in which case, the examiner should notify applicant in the next Office action that the information has not been considered.

See also Form Paragraph 6.49.06, which was used in informing applicant that the list of references did not constitute a proper IDS. Rather than questioning the examiner's integrity, it is recommended that applicant familiarize himself with the rules and procedures of patent prosecution. Documents cited on a proper IDS will be considered provided the criteria set forth in 37 §§ CFR 1.97 and 1.98, and MPEP §§ 609 and 1900 are adhered to. Documents merely

listed in the specification will not be cited on the face of a patent, should one issue from this application.

Claim Rejections - 35 USC §§ 112 and 101

9. Claims 1 – 8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of contacting cultured fibroblasts with agents under investigation wherein the pathological mechanism is manifest in both neural cells and fibroblasts, does not reasonably provide enablement for a method of screening for drugs which are candidates for treatment of all neurological diseases recited in independent claim 1, or for determining whether or not the agent in the screening assay should be selected as a drug candidate agent.

This rejection is maintained for the reasons of record. Before turning to the merits of the rejection, it is important to address applicant's misunderstanding of patent examination. Applicant states on p. 37 (final two paragraphs) of the remarks submitted 2 March 2006, that "the claims as written are dependent upon and limited by the Specification." While that may be applicant's hope, it is not consistent with USPTO policy. Limitations in the specification are not read in to the claims. While only certain diseases were mentioned in the specification, by claiming the invention generically (i.e. "establishing, from a patient having a predetermined neurological disease, a cell culture of fibroblast cells" as recited in claim 1, part c) the claim is considerably broader than what is disclosed. See MPEP § 2111, which states in part, in the discussion of In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969):

> The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.

Thus limitations in the specification are not read into the claims. Should applicant desire that certain limitations apply to the claims, applicant may want to consider actually reciting those limitations in the claims.

Turning to the merits of the rejection, the examiner notes that applicant did not refute any of the examiner's previously-stated reasoning but rather pointed to more limited

embodiments explained in the specification. The claims are given their broadest reasonable interpretation. Here, the claims are broad whereas the specification discloses much narrower embodiments. While claim 1 has now been amended to recite specific diseases, these appear in the preamble only and do not appear in the body of the claim. Claim 1, part (c) requires that a cell culture be established from a patient with "a predetermined neurological disease" but it does not require any particular disease. Note that the preamble does not necessarily limit the scope of the claim; see MPEP § 2111.02 for a more complete discussion of when the preamble does and does not limit the scope of the claim. In the instant case, it appears that the patient populations recited are an intended use of the method but the steps set forth in the body of the claim do not require any particular disease be present. Thus the rejection for unreasonable breadth of the claims that is not commensurate in scope with the disclosure stands.

Applicant further discusses the concept of prophetic examples and how these are not necessarily non-enabling (remarks, p. 39 for example). While prophetic examples of course can be enabling, they nonetheless must be commensurate in scope with the claims. The presence of working examples, as opposed to prophetic examples, is a strong indicator of enabled subject matter. See for example MPEP § 2164.01(a) for a discussion of the "Wands factors", which were explicitly listed in the paragraph spanning pp. 3 – 4 of the office action mailed 27 October 2005. As discussed in the previous office action, the specification is not enabling for the full breadth of screening assays claimed, is not enabling for all diseases as claimed and is not enabling for all uses of indicator systems as claimed. For the sake of brevity, the previous rejection, which appears on pp. 3 – 5 of the office action mailed 27 October 2005 will not be reiterated.

In order to overcome this rejection, it is recommended that applicant consider amending the claimed invention to be commensurate in scope with what is disclosed. See also MPEP § 2164.08 for a more thorough discussion of the enablement requirement and how it relates to the scope of the claims.

10. Claims 1 – 8 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for the reasons of record. Briefly, claim 1, part (d) provides for the use of an indicator system, but, since the claim does not set forth any steps involved in

the method/process, it is unclear what method/process applicant is intending to encompass. See MPEP § 2173.05(q). In the instant case, the claim requires "use" but does not recite adequate method steps. In order to overcome this rejection, it is recommended that applicant consider amending the claimed invention to actually recite the steps to be practiced in the course of the method. Recitation of verbs such as "performing an assay" or "detecting a protein" would be helpful. However, applicant is strongly cautioned against introducing new matter into the claims in order to overcome the rejection. See MPEP § 2163.05 – 2163.07 for a discussion of new matter.

11. Claims 1 – 8 stand rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

This rejection is maintained for the reasons of record. Note that "use" claims are to be rejected under both 35 USC 112, second paragraph and 35 USC 101; see MPEP § 2173.05(q).

Claim Rejections - 35 USC § 102

12. Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by May (1985. Journal of the Neurological Science 70:101-112, cited in previous office action), as evidenced by Kawagoe (1993. Journal of Neurochemistry 61:254-260).

This rejection is maintained for the reasons of record. Briefly, May teaches a method which encompasses each of the steps recited in claim 1. See office action mailed 27 October 2005, page 6, paragraph number 12. Applicant is reminded that terms in the claims are given their broadest reasonable interpretation and limitations in the specification are not read into the claims. Note that instant claim 1, part(d) recites "use of an indicator system capable of detecting stress protein expression". This is considerably broader than a requirement that any particular protein level be measured. Said indicator system need not accurately reflect actual stress protein levels, but merely has to be "capable of" detecting stress protein levels. The indicator system was the percentage of cells which are viable; since cells die upon sufficient levels of stress protein the viability assay corresponds to claim 1(d) as viability tests fairly anticipate use of an indicator system.

Applicant notes that May "never identified L-HCA or anything else as a 'chemical stress protein-inducing parameter'" (remarks, p. 41, last complete paragraph) and states that the examiner improperly attempts to read the disclosure into the prior art. Whether or not May explicitly identifies the compound as such is not required. The claim does not require explicit recognition of the compound, which is a mental step only. Rather claim 1 requires the steps recited therein, each of which is taught by May. As to hindsight, the examiner has done nothing more than read the claims in the broadest reasonable light, search and read the prior art, and indicate to applicant how every limitation recited in the claims is in fact anticipated by the prior art.

Applicant argues that the examiner's argument is flawed in four respects. Specifically, applicant argues that 1) the examiner has mistakenly inserted wording such as "stress protein expression" in the prior art, 2) the examiner has mistakenly determined that the trypan blue assay is an assay for stress protein expression, 3) the examiner has ignored certain concepts about preferential suppression of stress protein expression, and 4) May teaches away from the claimed invention. Applicant's arguments have been fully considered but they are not persuasive. Each point raised by applicant is addressed in order herein.

1) The examiner has not read words into the prior art that are not there. Rather the examiner has given the claim its broadest reasonable interpretation. Claim 1 does not require that stress protein expression be measured directly, or that any particular assay be used. Claim 1 only requires "use of an indicator system capable of detecting stress protein expression" (emphasis added). This is considerably broader than, for example, "measuring stress protein expression". Thus in searching and reading the prior art, the examiner properly looked for assays broader than those which explicitly measure expression of specific stress proteins.

2) As explained above, the breadth of the expression "use of an indicator system capable of detecting stress protein expression" allows for any assay, or any indicator system so long as that system is capable of detecting stress protein expression. Trypan blue is a cell viability assay. When cells undergo very high degrees of stress, they first express increased amount of stress proteins and then die. While some hypothesize that the increased stress protein expression is a compensatory mechanism to the stress, that does not change the fact that cells frequently show increased stress protein expression prior to death. Thus using a cell viability assay such as trypan blue certainly meets the limitation "use of an indicator system

capable of detecting stress protein expression", since it measures cell viability and thus is capable of detecting stress protein expression.

3) Applicant argues that the examiner has ignored certain concepts about whether preferential suppression of stress protein expression. While it may be applicant's intention to have such limitations read into the claims, they are not actually present. Applicant notes that the changes in cell viability were dependent upon the presence of other chemicals. However, whether or not this is the case is immaterial as the prior art teaches every step of the claimed invention. Note further that claim 1 uses the word "comprising" as the transitional phrase, which allows for additional elements beyond those recited in the claim. Because the claim is written broadly and given its broadest reasonable interpretation, and because the prior art teaches every step of the claimed method, the rejection stands.

4) With respect to the argument that May teaches away from the invention now claimed, applicant appears to be confusing the standards for rejections under 35 USC §§ 102 and 103. Rejections under 35 USC § 103 can sometimes be overcome by persuasively arguing that the prior art teaches away from the claimed invention, thereby guiding artisans of ordinary skill not to do what an inventor had done; see MPEP §§ 2144.05(III) and 2145(X). In contrast, such arguments are not germane to discussions of rejections for anticipation under 35 USC 102; see MPEP § 2131.05.

Claim Rejections - 35 USC § 103

13. Claims 1, 2, and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over May (1985. Journal of the Neurological Science 70:101-112, cited in previous office action), Berberian (WO 91/15219, published 17 October 1991), and Ide (1995. Biochemical and Biophysical Research Communication 209:1119-1125).

This rejection is maintained for the reasons of record and explained in further detail herein. Briefly, May teaches a screening assay that uses the six groups of fibroblasts recited in claim 1, as set forth in the rejection under 35 USC 102(b). However May does not teach antibodies specific for stress proteins indicative of oxidative stress or resolution of stress proteins according to molecular weight.

Berberian teaches methods of detecting heat shock protein 70 (HSP 70), using primary antibodies specific for the stress protein (antibody N27F34, which Berberian teaches is specific for two forms of HSP 70) followed by anti immunoglobulin HRP-conjugated secondary antibody

and also using gel electrophoresis. See p. 16, lines 14 – 27. Berberian also teaches that HSP 70 is induced by the presence of abnormal proteins (see p. 2 lines 15 – 31). However, Berberian does not teach detecting HSP 70 in fibroblasts from patients with Huntington's disease and does not teach the screening method taught by May.

Ide teaches that Huntington's disease leads to the presence of abnormal proteins within the cell. Specifically, the 350kDa protein, named p350 in Ide (and now known as Huntingtin) shows an increased molecular mass in tissue from patients with Huntington's disease and thus provides motivation to the artisan of ordinary skill to detect HSP 70 in tissue from HD patients, since Berberian teaches that abnormal proteins (i.e., those present in Hutington's disease) induces HSP 70. However, Ide does not teach detecting HSP 70 and does not teach the screening method taught by May.

It would have been obvious to one of ordinary skill in the art to screen drugs using the method of May, and to use either a combination of primary and secondary antibodies or gel electrophoresis, as taught by Berberian, with a reasonable expectation of success. The motivation for using the antibody method would be to detect HSP 70, as Berberian teaches HSP 70 is induced by abnormal proteins and Ide teaches that Huntington's disease is characterized by abnormal proteins.

Applicant argues that the examiner has improperly taken contradictory positions as to the role of HSP 70 in the cell. This is simply not true. The examiner has noted that trypan blue is "capable of detecting stress protein expression", not that HSP 70 causes cell death. Both cell death and stress protein expression many be caused by some other insult. In the instant rejection under 35 USC 103, the examiner has noted that the prior art references by May, Berberian, and Ide, taken together, guide the artisan of ordinary skill to measure the specific stress protein HSP70 by the methods recited in claims 2 and 4. Thus the rejection stands.

14. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over May, Berberian, and Ide as applied to claims 1, 2, and 4 above, and further in view of Savage et al. (1992. Avidin-Biotin Chemistry: A Handbook. Rockford, Illinois: Pierce Chemical Company, pp. 191 – 194).

This rejection is maintained for the reasons of record. As a preliminary point, claims 1, 2, and 4 were not explicitly listed in the first clause of the rejection in the previous office action (see office action mailed 27 October 2005, page 8, paragraph 15). However, as claims 1, 2,

and 4 were all indicated as obvious over May in view of Berberian and Ide, the failure to explicitly recite them in the statement of rejection herein was a typographic error only. Thus inclusion of these claims in the present rejection does not constitute a new grounds of rejection.

The reasons why claims 1, 2, and 4 are obvious over May in view of Berberian and Ide are set forth in the first rejection under 35 USC 103 above. However, none of May, Berberian, or Ide teach antibody-indicator conjugates include biotin. Savage teaches detection in immunohistochemical techniques using biotin, as it relates to claim 3. Applicant did not traverse the examiner's determination that immunohistochemical techniques using biotin are obvious once antibody-indicator conjugates recited in claim 2 are obvious. Thus the rejection stands for the reasons of record.

On p. 45 of the remarks, applicant states that "the Examiner's assertion that the instant disclosure was presented earlier... is incorrect". Note that the disclosure is not what is rejected, but the invention as set forth in the claims.

15. Claims 1 and 5 – 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over May (1985. Journal of the Neurological Science 70:101-112, cited in previous office action), in view of Bowling (1995. Life Sciences 56(14):1151-1171) and Levine (1994. Methods in Enzymology 233:346-357).

This rejection is maintained for the reasons of record. Applicant did not specifically traverse the rejection beyond stating that "the Examiner's attempt to supplement his initial mistake with one of many reports on oxidative stress... fails to correct the original mistake." (remarks, p. 45) As applicant did not specifically point out errors in the examiner's scientific or legal reasoning, the rejection of claims 1 and 5 – 8 stands for the reasons made of record previously.

16. On p. 46 of the remarks, applicant indicates that a reference was cited on PTO-892 and a copy thereof was included but there reference itself was not discussed in the office action. The reference was cited and included due to an oversight on the examiner's part. The examiner regrets any confusion this may have caused.

Conclusion

17. No claim is allowed.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of $500 ($250 for a small entity, if such status has been obtained by applicant).

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Applicant may also file a Request for Continued Examination pursuant to 37 CFR 1.114.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
January 4, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER